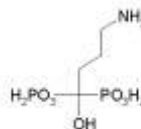


Rx **ALENDRONATE**

(Alendronate is in a class of medications called bisphosphonates)



100% EXPORT QUALITY MEDICINE



GENERIC NAME: alendronate

DRUG CLASS AND MECHANISM

Alendronate is in a class of medications called bisphosphonates. The bisphosphonate class includes etidronate (Didronel), ibandronate (Boniva), pamidronate (Aredia), risedronate (Actonel), and tiludronate (Skelid). Bisphosphonates are used for treating osteoporosis (reduced density of bone that leads to fractures) and bone pain from diseases such as metastatic breast cancer, multiple myeloma, and Paget's disease. Bone is in a constant state of remodeling. New bone is laid down by cells called osteoblasts while old bone is removed by cells called osteoclasts. Bisphosphonates strengthen bone by inhibiting bone removal (resorption) by osteoclasts. After menopause, there is an increased rate of bone loss leading to osteoporosis, and alendronate has been shown to increase bone density and decrease fractures of bones. The FDA approved alendronate in September 1995.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATIONS: Tablets: 5, 10, 35, 40, 70 mg. Solution: 70 mg

PRESCRIBED FOR

Alendronate is used for treating osteoporosis in men and postmenopausal women. It also is used for Paget's disease of bone and osteoporosis caused by steroid treatment. Non-FDA approved (off-label) uses include vitamin D overdose and osteoporosis caused by spinal injury.

DOSING

The recommended dose for treatment of osteoporosis is 5-10 mg daily or 35-70 mg weekly. Paget's disease is treated with 40 mg once daily for six months.

Since food, other medications, and vitamins can interfere with the absorption of alendronate, they should be taken at least 30 minutes before alendronate. In order to avoid chemical irritation of the esophagus (the swallowing tube that connects the mouth with the stomach), alendronate should be taken with a full glass of plain water immediately upon arising in the morning and never chewed or sucked. It should be avoided by patients with abnormalities of the esophagus which delay esophageal emptying, such as scarring (stricture) or poor motility (achalasia). Patients should also not lie down for 30 minutes after swallowing the tablets. Those patients who are unable to remain upright for at least 30 minutes after taking alendronate should not take it.

DRUG INTERACTIONS

Calcium supplements and antacids reduce the absorption of alendronate. Therefore, alendronate should be taken at least 30 minutes before calcium and antacids.

Intravenous ranitidine (Zantac) increases blood levels of alendronate. The importance of this reaction is unknown.

The risk of stomach and intestinal side effects may increase when alendronate is combined with aspirin or other nonsteroidal antiinflammatory drugs (NSAIDs).

SIDE EFFECTS

The most common side effect of alendronate is stomach pain. It also may cause nausea, vomiting, bloating, constipation, diarrhea, gas, black stool (due to intestinal bleeding), change in taste perception, and muscle or joint pain. Alendronate may irritate the esophagus, causing ulcers and bleeding. This occurs more often when patients do not drink enough water with alendronate, wait 30 minutes before lying down, or take alendronate before the first meal of the day. Rarely, patients may experience jaw problems (osteonecrosis of the jaw) associated with delayed healing and infection after tooth extraction.

Bone, joint, and muscle pain also can occur as can femoral fractures.

USES

Alendronate is used to prevent and treat certain types of bone loss (osteoporosis). It belongs to a class of medications called bisphosphonates, and they decrease the activity of cells which break down bone. Maintaining strong bones by slowing bone loss helps to reduce the risk of fractures. Your risk of developing osteoporosis is greater as you age, after menopause due to the lack of natural estrogen hormones, and if you are taking corticosteroid medications (e.g., prednisone) for long periods.

HOW TO USE

Follow these instructions very closely to maximize the amount of drug absorbed and reduce the risk of injury to your esophagus. This medicine comes with a patient information leaflet. Read it carefully. Ask your doctor or pharmacist any questions you may have about this medicine. Take this medication by mouth once a day, after getting up for the day and before taking your first food, beverage or other medication. Take it with a full glass (6-8 oz.

or 180-240 ml) of plain water. Swallow the tablet whole. Do not chew or suck on it. Then stay fully upright (sitting, standing or walking) for at least 30 minutes and do not lie down until after your first food of the day. Wait at least 30 minutes after taking the medication before you eat or drink anything other than plain water. Do not take this medication at bedtime or before rising for the day. It may not be absorbed and you may have side effects. Other medications, vitamins, antacids, coffee, tea, soda, mineral water and food can decrease the absorption of alendronate. Do not take these for at least 30 minutes after taking alendronate. Use this medication regularly to get the most benefit from it. Remember to use it at the same time each morning.

SIDE EFFECTS

Stomach pain, constipation, gas, or nausea may occur. If these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: jaw pain, an increase in muscle or bone pain, black stools, vomit that looks like coffee grounds. This medication may infrequently cause serious irritation and ulcers of the esophagus. If you notice any of the following unlikely but very serious side effects, stop taking alendronate and consult your doctor or pharmacist immediately: new or worsening heartburn, chest pain, trouble or painful swallowing. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking alendronate, tell your doctor or pharmacist if you are allergic to it; or to other bisphosphonates; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: disorders of the esophagus (e.g., esophageal stricture or achalasia), inability to stand or sit upright for at least 30 minutes, low calcium levels, severe kidney disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: trouble swallowing, stomach/intestinal disorders (e.g., ulcers). Infrequently, serious jawbone problems (osteonecrosis) have occurred in people taking similar medication. Most people were also using other medications or had conditions which might have actually caused the jawbone problem. If you have cancer, anemia, blood clotting disorders, infections in the mouth or other diseases of the mouth, or poor dental hygiene, see your dentist for a full examination/treatment before you start alendronate. Make sure he/she knows your entire medical history, any cancer radiation treatments, and also all the medications you are using, especially corticosteroids such as prednisone, cancer chemotherapy, and alendronate. Consult your dentist for more details. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: severe stomach pain, painful heartburn, pain in the esophagus (chest pain), muscle weakness, mental/mood changes.

MISSED DOSE

If you miss a dose, skip the missed dose. Resume your usual dosing schedule the following day. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010